

## **Remarks**

### **1. Status and Support**

Claims 1-18 are currently pending. Support for the amendment to claim 1 and new claim 29 can be found, for example, in paragraphs 7-8, 10, 14, and 29. Amendments to claims 23 and 28 are supported, for example, in paragraph 29 and 31 and original claim 24. Thus, no new matter has been introduced as a result of these amendments.

The above amendments to the claims are made without prejudice to the subject matter of those claims, and are made merely in order to expedite prosecution of the application. Applicants expressly reserve the right to pursue the subject matter of those claims in this or a timely filed continuing application. The amendments to the claims should not be construed as conceding or acquiescing to the basis of any of the prior or pending rejections.

### **2. Rejections under 35 U.S.C. § 112, second paragraph**

Claims 1-22 and 27 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Patent Office asserts that the claims are incomplete for omitting essential steps and that the “omitted steps are: Introducing the sample containing an analyte to come into contact with the metal complex.” Independent claim 1 has been amended, thereby obviating the rejection for claims 1-22. Claim 27 does not contain any recitation of analytes or sample and thus, is not incomplete, nor is it missing the steps as asserted by the Patent Office. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection.

### **3. Rejections under 35 U.S.C. § 102(e)**

Claims 1-4, 6, 8-10, 13-16, 23, 26-28 are rejected under 35 USC §102(e), as anticipated by Kumar et al (US 2004/0090168 and provisional application 60/390816). Applicants traverse this rejection.

As stated in the MPEP, “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).” (MPEP §2131).

Currently pending claim 1 recites the following:

*A method for detecting an analyte in a sample using a luminescent metal complex as a labelling group, comprising*

- (i) oxidizing a metal complex;*
- (ii) reducing the metal complex by nascent hydrogen to produce a form of the metal complex that is capable of chemiluminescing, wherein the oxidizing in step (i) and the reducing in step (ii) take place in separate reaction chambers;*
- (iii) contacting a sample containing an analyte with a detection reagent which carries the metal complex that is capable of chemiluminescing; and*
- (iv) determining the analyte by means of the chemiluminescence.*

In contrast, Kumar does not teach or suggest all of the claim limitations. For example, Kumar does not teach or suggest at least the following claim limitations of claim 1: “(ii) reducing the metal complex by nascent hydrogen to produce a form of the metal complex that is capable of chemiluminescing, and the recited oxidizing and reducing steps (reducing by nascent hydrogen) taking place in separate reaction chambers.

The Patent Office asserts that Kumar teach a “method and apparatus for detecting an analyte in a sample using a luminescent metal complex...” The Patent Office further asserts that Kumar teaches “(ii) introducing hydrogen gas (“nascent hydrogen”, hydrogen gas inherently reduces the metal complex by nascent hydrogen to produce a form of the metal complex that is capable of chemiluminescing) by applying a -1.5V (Pg. 17, lines 1-11);...” Applicants respectfully point out that the Patent Office’s assertion is based upon a misunderstanding of the teachings of Kumar. The sections of Kumar cited by the Patent Office do not deal with reducing a metal complex by nascent hydrogen (much less the generation of chemiluminescence) as recited in the pending claims, but rather with the cleaning of the redox device (paragraph [0057]). The hydrogen generated according to Kumar, exclusively serves the purpose of cleaning the electrochemical cell; Kumar provides

no teaching of reducing the metal complex by nascent hydrogen as recited by the pending claims. As taught in Kumar:

*Subsequent to the generation and measurement of ECL from the sample, the assay cell is preferably cleaned and prepared for measuring a new sample. In one embodiment, a cleaning solution (typically a basic solution comprising a detergent) is introduced and a series of cleaning potentials are applied. It has been found that it is especially advantageous for cleaning to use oxidizing or reducing potentials that are sufficient to generate oxygen or hydrogen gas on the electrode surfaces.*

Thus, Kumar clearly does not teach or suggest “reducing the metal complex by nascent hydrogen...”, much less doing so resulting in production of “a form of the metal complex that is capable of chemiluminescing” and only makes mention of hydrogen as a way to clean the redox device. This is an important distinction. There is no other discussion of hydrogen anywhere in Kumar except with respect to cleaning/purification as opposed to the methods and device of the instant invention which recites using hydrogen to reduce metal complexes to produce a form of the metal complex capable of luminescing. Nor does Kumar teach the recited oxidizing and reducing steps (reduction by nascent hydrogen) taking place in separate reaction chambers. Thus, Kumar does not teach all of the claim limitations of pending claim 1 (or 27), nor of its dependent claims.

Furthermore, Kumar does not teach all of the limitations of the device of pending claim 23 (or dependent claims 24-26) or 28, which recite that the means for oxidizing and the means for generating nascent hydrogen comprise two separate reaction chambers. There is no teaching, suggestion, or motivation in Kumar for the use of such separate means for oxidizing and the means for generating nascent hydrogen.

Based on all of the above, Applicant respectfully request reconsideration and withdrawal of the rejection.

#### **4. Rejections under 35 U.S.C. § 103(a)**

**A.** Claim 5 is rejected under 35 USC §103(a), as being obvious over Kumar in view of Josel et al (USP 5,958,783).

In order to establish a *prima facie* case of obviousness the Patent office must establish that the prior art references alone or in combination must teach or suggest *all* the claim limitations. MPEP § 706.02(j).

Claim 5 is dependent on claim 1 and thus shares all of the claims limitations of independent claim 1. The instant rejection is based, in part, on the rejection of independent claim 1 over Kumar, which the patent Office asserts teaches all of the limitations of claim 1. As argued above in point (3), the Patent Office has misunderstood the teachings of Kumar, which, in fact, does not teach, suggest or make obvious all of the limitations of claim 1. Kumar teaches the use of hydrogen for the purpose of cleaning a redox device and does not teach, suggest, or make obvious “reducing the metal complex by nascent hydrogen to produce a form of the metal complex that is capable of chemiluminescing” as recited in claim 1. Nor does Kumar teach the recited oxidizing and reducing steps (reduction by nascent hydrogen) taking place in separate reaction chambers. Josel is asserted to teach that “it is advantageous to introduce[d] a free positive or/and negative carriers into the linker.” Josel does not teach, suggest or make obvious the use of nascent hydrogen to produce a form of the metal complex that is capable of chemiluminescing, nor the recited oxidizing and reducing steps (reduction by nascent hydrogen) taking place in separate reaction chambers. Thus, the combination of Kumar in view of Josel does not cure the deficiency of Kumar. Thus, the combination of Kumar in view of Josel does not teach suggest or make obvious all of the limitations of independent claim 1 or its dependent claims including claim 5. Therefore, Applicant respectfully request reconsideration and withdrawal of the rejection.

**B.** Claims 7, 11-12, 21 and 25 are rejected under 35 USC §103(a), as being obvious over Kumar in view of Bard et al (USP 5,714,089).

In order to establish a *prima facie* case of obviousness the Patent office must establish that the prior art references alone or in combination must teach or suggest *all* the claim limitations. MPEP § 706.02(j).

Claims 7, 11-12, and 21 are dependent on claim 1 and claim 25 is dependent on claim 23 and thus shares all of the claims limitations of independent claim 1 or claim 23. The

instant rejection is based, in part, on the rejection of independent claim 1 over Kumar, which the patent Office asserts teaches all of the limitations of claim 1. As argued above in point (3), the Patent Office has misunderstood the teachings of Kumar, which, in fact, does not teach all of the limitations of claim 1. Kumar teaches the use of hydrogen for cleaning a redox device and does not teach, suggest, or make obvious “reducing the metal complex by nascent hydrogen to produce a form of the metal complex that is capable of chemiluminescing” as recited in claim 1 or as recited in claim 23. Nor does Kumar teach the recited oxidizing and reducing steps (reduction by nascent hydrogen) taking place in separate reaction chambers. Bard is asserted to teach that “Ru(bpy)<sub>3</sub> can be oxidized by either chemically by PBo<sub>2</sub> or Cer<sup>4+</sup> compounds or electrochemically.” Bard does not teach, suggest or make obvious the use of hydrogen to produce a form of the metal complex that is capable of chemiluminescing, nor does Bard teach or suggest the recited oxidizing and reducing steps (reduction by nascent hydrogen) taking place in separate reaction chambers. Thus, the combination of Kumar in view of Bard does not cure the deficiency of Kumar with respect to claims 1 and 23. Thus, the combination of Kumar in view of Bard does not teach suggest or make obvious all of the limitations of independent claims 1 or 23 or their dependent claims including claims 7, 11-12, 21 and 25. Therefore, Applicant respectfully request reconsideration and withdrawal of the rejection.

C. Claims 17-18 are rejected under 35 USC §103(a), as being obvious over Kumar in view of Harris et al. (USP 4,842,844).

In order to establish a *prima facie* case of obviousness the Patent office must establish that the prior art references alone or in combination must teach or suggest ***all*** the claim limitations. MPEP § 706.02(j).

Claims 17-18 are dependent on claim 1 and thus share all of the claims limitations of independent claim 1. The instant rejection is based, in part, on the rejection of independent claim 1 over Kumar, which the patent Office asserts teaches all of the limitations of claim 1. As argued above in point (3), the Patent Office has misunderstood the teachings of Kumar, which, in fact, does not teach all of the limitations of claim 1. Kumar teaches the use of hydrogen for cleaning a redox device and does not teach, suggest, or make obvious “reducing the metal complex by nascent hydrogen to produce a form of the metal complex that is capable of chemiluminescing” as recited in claim 1. Nor does Kumar

teach the recited oxidizing and reducing steps (reduction by nascent hydrogen) taking place in separate reaction chambers. Harris is asserted to teach that “the generation of hydrogen by reacting hydrochloric acid gas and zinc.” Harris does not teach, suggest or make obvious the use of hydrogen to produce a form of the metal complex that is capable of chemiluminescing, nor does Harris teach or suggest the recited oxidizing and reducing steps (reduction by nascent hydrogen) taking place in separate reaction chambers. Thus, the combination of Kumar in view of Harris does not cure the deficiency of Kumar with respect to independent claim 1. Thus, the combination of Kumar in view of Harris does not teach suggest or make obvious all of the limitations of independent claim 1 or its dependent claims including claims 17-18. Therefore, Applicant respectfully request reconsideration and withdrawal of the rejection.

**D.** Claim 19-20 are rejected under 35 USC §103(a), as being obvious over Kumar in view of Riesz et al. (Environmental Health Perspectives Vol. 64, pp 233-252, 1985).

In order to establish a *prima facie* case of obviousness the Patent office must establish that the prior art references alone or in combination must teach or suggest ***all*** the claim limitations. MPEP § 706.02(j).

Claims 19-20 are dependent on claim 1 and thus share all of the claims limitations of independent claim 1. The instant rejection is based, in part, on the rejection of independent claim 1 over Kumar, which the patent Office asserts teaches all of the limitations of claim 1. As argued above in point (3), the Patent Office has misunderstood the teachings of Kumar, which, in fact, does not teach all of the limitations of claim 1. Kumar teaches the use of hydrogen for cleaning a redox device and does not teach, suggest, or make obvious “reducing the metal complex by nascent hydrogen to produce a form of the metal complex that is capable of chemiluminescing” as recited in claim 1. Nor does Kumar teach the recited oxidizing and reducing steps (reduction by nascent hydrogen) taking place in separate reaction chambers. Riesz is asserted to teach “the method of using ultrasound in aqueous solutions to generate hydrogen.” Riesz does not teach, suggest or make obvious the use of hydrogen to produce a form of the metal complex that is capable of chemiluminescing, nor does Riesz teach or suggest the recited oxidizing and reducing steps (reduction by nascent hydrogen) taking place in separate reaction chambers. Thus,

the combination of Kumar in view of Riesz does not cure the deficiency of Kumar with respect to independent claim 1. Thus, the combination of Kumar in view of Riesz does not teach suggest or make obvious all of the limitations of independent claim 1 or its dependent claims including claims 19-20. Therefore, Applicant respectfully request reconsideration and withdrawal of the rejection.

E. Claims 22 and 24 are rejected under 35 USC §103(a), as being obvious over Kumar in view of Welk (CA 2313144).

In order to establish a *prima facie* case of obviousness the Patent office must establish that the prior art references alone or in combination must teach or suggest ***all*** the claim limitations. MPEP § 706.02(j).

Claim 22 is dependent on claim 1 and claim 24 is dependent on claim 23 and thus the claims share all of the claims limitations of independent claim 1 or claim 23. The instant rejection of claim 22 is based, in part, on the rejection of independent claim 1 over Kumar, which the patent Office asserts teaches all of the limitations of claim 1. As argued above in point (3), the Patent Office has misunderstood the teachings of Kumar, which, in fact, does not teach all of the limitations of claim 1. Kumar teaches the use of hydrogen for cleaning a redox device and does not teach, suggest, or make obvious “reducing the metal complex by nascent hydrogen to produce a form of the metal complex that is capable of chemiluminescing” as recited in claim 1. Nor does Kumar teach the recited oxidizing and reducing steps (reduction by nascent hydrogen) taking place in separate reaction chambers. Welk is asserted to teach “an electrolytic cell for the generation of nascent hydrogen and oxidizing agents wherein there are separate chambers for the positive and negative electrodes (abstract).” Welk does not teach, suggest or make obvious the use of hydrogen to produce a form of the metal complex that is capable of chemiluminescing, nor does Welk teach of suggest the recited oxidizing and reducing steps (reduction by nascent hydrogen) taking place in separate reaction chambers. Thus, the combination of Kumar in view of Welk does not cure the deficiency of Kumar with respect to claim 1, or its dependent claim 22.

Furthermore, Kumar does not teach all of the limitations of the device of pending claim 23 (or dependent claim 24), which recite that the means for oxidizing and the means for generating nascent hydrogen comprise two separate

reaction chambers. There is no teaching, suggestion, or motivation in Kumar for the use of such separate means for oxidizing and the means for generating nascent hydrogen. Welk does not cure this deficiency, and thus the combination of Kumar and Welk does not teach or suggest all of the limitations of claims 23 or its dependent claim 24.

Based on all of the above, the combination of Kumar in view of Welk does not teach suggest or make obvious all of the limitations of independent claims 1 or 23 or their dependent claims including claims 22 and 24. Therefore, Applicant respectfully request reconsideration and withdrawal of the rejection.

## **5. Conclusion**

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended or as originally presented. Allowance of the claims is thereby respectfully solicited.

If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned representative as indicated below at 312-913-2106.

Respectfully submitted,  
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